

REMARKS

Claims 1-14 are pending in the application.

Claim 14 has been objected to based upon a restriction requirement.

Claims 1-13 have been rejected.

Claims 1, 6, 8, 11 and 14 have been amended, as set forth herein.

New Claims 15-19 have been added.

I. **RESTRICTION OF CLAIM 14**

The Office Action argues that Claim 14 is subject to restriction because it is directed to an invention that is independent or distinct from the invention as originally claimed because Claim 14 has the following limitations not found in independent Claims 1, 4, 6, 8 and 11: “at least one waisted region,” “a first electrode and a second electrode” and “wherein the waisted region is positioned between the first electrode and the second electrode.” This restriction requirement is respectfully traversed.

The Office Action appears to argue that since Claim 14 includes a limitation not present in the original independent Claims 1, 4, 6, 8 and 11, therefore such invention claimed in Claim 14 must be independent or distinct. The Office Action has failed to provide a proper basis to support the present restriction requirement that Claim 14 is directed to an invention that is independent or distinct from the invention as originally claimed. Moreover, and contrary to the Office Action assertions, the element “at least one waisted region” is set forth in independent Claims 8 and 11, and

the element “a first electrode and second electrode” is set forth in independent Claims 1, 4, 6, 8 and 11 (recited as “a plurality of electrodes”). As such, independent Claim 11 and 14 both include these elements (as well as other similar elements, such as “planar surfaces”, “greatest transverse dimension”, “plurality of terminals”, “plurality of conductors”, etc.). Independent Claim 14 further recites “wherein the waisted region is positioned between the first electrode and the second electrode”. Accordingly, the Applicant respectfully submits that Claim 14 is not independent or distinct from the currently pending claims, and the Office Action has failed to establish a prima facie case that the invention as claimed in Claim 14 is independent or distinct.

Accordingly, the Applicant respectfully requests withdrawal of the restriction of Claim 14.

II. REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-13 were rejected under 35 U.S.C. § 102(e) as being anticipated by King, et al. (US 6,161,047). Claims 1-7 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kuzma, et al. (US 6,522,932). Claims 1-13 were rejected under 35 U.S.C. § 102(e) as being anticipated Errico, et al. (US 6,175,769). The rejections are respectfully traversed.

A cited prior art reference anticipates the claimed invention under 35 U.S.C. § 102 only if every element of a claimed invention is identically shown in that single reference, arranged as they are in the claims. MPEP § 2131; *In re Bond*, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). Anticipation is only shown where each and every limitation of the claimed invention is

found in a single cited prior art reference. MPEP § 2131; *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applicant has amended independent Claims 1, 6, 8 and 11 (and independent Claim 14 to recite that a greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure. (emphasis added)

With respect to King, King's lead expands, and thus fails to provide a lead wherein the greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure. See, Claims 1, 6, 8 and 11, as amended. As previously noted, King further fails to disclose that the lead body has a varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Claim 4. The Office Action argues that the varying transverse dimension of the lead in both the compacted (Figure 10A) and natural (Figure 10B) positions leads to flexibility as claimed by Applicant. Applicant respectfully submits that there is no description that King's lead body is even flexible, or flexible (more or less rigidity) due to the varying transverse dimensions. Such a conclusion is insupportable from viewing Figures 10A or 10B.

With respect to Kuzma, Kuzma's lead expands, and thus fails to provide a lead wherein the greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure. See, Claims 1 and 6, as amended. As previously noted, Kuzma further fails to disclose that the lead body has varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides

steerability of the lead. See, Claim 4. The Office Action argues that the varying transverse dimension of the lead, by virtue of the columns of electrodes (Figure 7A, 42a, 42b) leads to flexibility as claimed by Applicant. Applicant respectfully submits that the electrodes (42a, 42b) of Kuzma fail to show a varying transverse dimension. Applicant respectfully submits that there is no description of any varying transverse dimension, let alone a description that Kuzma's lead body is even flexible (in a plane substantially parallel to the principal surfaces of the body of the lead).due to the varying transverse dimensions. Such a conclusion is unsupported from viewing Figure 7A (and electrodes 42a,42b).

With respect to Errico, Errico recites a paddle-type structure with an extending portion for suturing to the tissue. Errico does not appear to disclose or mention "percutaneous" insertion or a "percutaneous insertion structure" or "percutaneously accessing." Moreover, Errico discloses that "by techniques already known in the field of spinal surgery, the surgeon would place the electrode beneath the lamina . . ." (emphasis added). Col. 3, lines 41-44. As such, the foregoing teaching of Errico coupled with Errico's Figures 1 and 2 (that illustrate an enormous paddle structure) provide sufficient evidence that Errico's lead is not inserted percutaneously. Accordingly, Errico fails to disclose a lead body wherein a greatest transverse dimension of the lead is less than a corresponding interior dimension of a percutaneous introduction structure. See, Claims 1, 6, 8 and 11, as amended. Further, Errico fails to disclose that the lead body has varying transverse dimension that enables flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. See, Claim 4.

Accordingly, the Applicant respectfully requests the Examiner withdraw the § 102(e) rejections of Claims 1-13.

III. REJECTION UNDER 35 U.S.C. § 103

Claims 1-13 were alternatively rejected under 35 U.S.C. § 103(a) as being unpatentable over Errico, et al. (US 6,175,769) in view of Kohnen, et al. (US 6,249,707). The rejection is respectfully traversed.

In *ex parte* examination of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of nonobviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 U.S.P.Q. 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2142.

As previously described, Errico recites a paddle-type structure with an extending portion for suturing to the tissue. Errico's method of implant is by surgery, not percutaneous insertion. As such, the foregoing teaching of Errico coupled with Errico's Figures 1 and 2 (that illustrate an enormous paddle structure) provide sufficient evidence that Errico's lead is not inserted percutaneously. In fact, Errico recites a history of different implanting methods, from initial methods using invasive techniques (surgery), then using percutaneous methods, then reverting back to invasive techniques, and then back to percutaneous insertion techniques. The problem with the latest percutaneous techniques, as described in Errico, was the inability to fix the electrode at the appropriate location. Col. 1, lines 20-65. Thus, Errico appears to describe surgical implantation (not percutaneous implantation) of a paddle-type lead and suturing of the lead to tissue to prevent movement of the

lead. As such, Errico teaches away from percutaneous insertion techniques, and thus there is no teaching or suggestion to combine Errico with Kohnen, as asserted by the Office Action. Therefore, there is no suggestion or motivation in the references to modify the reference or to combine reference teachings, and none of the references, either alone or in combination, disclose, teach or suggest the Applicant's invention as claimed.

Accordingly, the Applicant respectfully requests withdrawal of the § 103 rejection of Claims 1-13.

IV. NEW CLAIMS 15-19

Applicant has added new Claim 15-19, and believes that it is patentable over the art of record.

V. CONCLUSION

As a result of the foregoing, the Applicant asserts that the remaining Claims in the Application are in condition for allowance, and respectfully requests an early allowance of such Claims.

If any issues arise, or if the Examiner has any suggestions for expediting allowance of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at *rmccutcheon@davismunck.com*.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

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Date: 4/27/2004


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